DETAILED ACTION

Requirements for information, to request information on duty of disclosure

1. The applicant has submitted an IDS containing 698 number of reference on 03/12/2008, reminds the applicant that it is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance.

Therefore, it is required that if any information that is known to be material for patentability as defined by 37 C.F.R. § 1.56, applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

(37 CFR 1.105, MPEP 704.10 [R-3] , MPEP 2004 [R-2] (13))

Election/Restrictions

2. A response on 10/09/2008 a provisional election was made without traverse to prosecute the invention of claims 55-69 and 73. Claims 41-54, 70-72 and 74-142 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Because these inventions are distinct for the reasons given on action 06/18/2008, the restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b)

if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Newly submitted claims 143-148 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

A first species as best illustrated in claims 55-69 and 73.
A second species as best illustrated in claims 143-148.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species (MPEP 806.04(f)) . In addition, these species are not obvious variants of each other based on the current record. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.
For example the cited section contain mutually exclusive characteristics, original set of claims (55-69 and 73) claims a device for monitoring glucose concentration in a biological sample of a host, by data point matching with rate of change with threshold reference.

Claims 143-148 claims a device for monitoring glucose concentration in a biological sample of a host, the device including instructions configured to cause the processor to not recalibrate and/or update calibration of the data stream using a glucose concentration measured by the single point glucose monitor when the rate of change of the calibrated data stream is outside a physiologically feasible limit.

Species are always the specifically different embodiments. Species (maybe either) independent or related as disclosed (See MPEP 806.04(e) and 806.04(b)) Note: in this case, the species are best illustrated using claims, MPEP 809.02(a) [R-3]). It is noted that numerous additional embodiments have been disclosed in the specification. Should Applicant introduce claims directed to additional species or amend the claims to be directed toward species distinct from the elected species, the claims may be subject to further restriction. (See 37 CFR 1.142(b) and MPEP § 821.03.)

In view of the above evidence, in the original presentation, present distinct patentable subject matter. It would have been a restriction in the first office action in the merits if the newly presented claims were in the original presentation. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 143-148 withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03

Joint inventor

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 69, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Joseph Jeffrey (WO 97/01986, January 23, 1997).

Regarding claim 55:

Joseph Jeffrey describes a device for monitoring glucose concentration in a biological sample of a host (page8), the device comprising: a substantially continuous glucose sensor that produces a data stream indicative of a glucose concentration in a host (page 9) the data stream comprising a plurality of time spaced sensor data points (page 9); an integrated receiver that receives the data stream from the substantially continuous glucose sensor (page 9, 10, fig. 13), wherein the integrated receiver comprises: a single point glucose monitor (fig. 18a, unit 420) configured to receive a biological sample from the host and to measure the concentration of glucose in the sample (fig. 18a, 18c, unit 330), the measured glucose concentration (page 11) comprising a reference data point (page 35, 36); a processor (fig. 13A, unit 300); and a computer readable memory (fig. 13A, unit 300) comprising: instructions configured to cause the processor to process the data stream received from the continuous glucose sensor (page 35, fig. 13A, 300, 330); instructions configured to cause the processor to determine a rate of change of the data stream from the substantially continuous analyte sensor (fig. 13d); and instructions configured to cause the processor to calibrate the data stream (page 28) using the glucose concentration measured by the single point glucose monitor (page 28, 31, 34, 35, 36 weekly calibration if needed using blood for glucose information, claim 24).

Regarding claim 56, Joseph Jeffrey further describes the reference input module is configured to reject a reference data point obtained when the rate of

change of the data stream is above a threshold (page 35, noise removal algorithms).

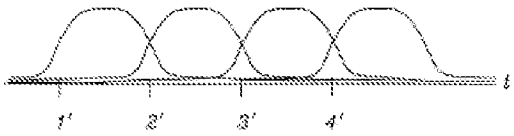


FIG. 13d

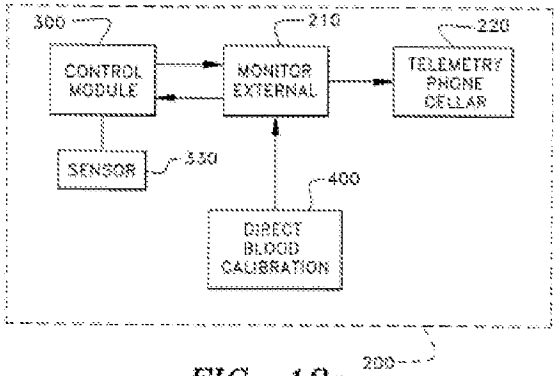


FIG. 13a

Regarding claim 57, Joseph Jeffrey further describes a data matching module configured to match a reference data point to a sensor data point to form a matched data pair (page 25, to calculate pulse wave velocity from sensor pair, page 35, multispectral correlation), wherein the reference data point and the sensor data point are obtained at substantially corresponding times (fig. 13d, 13b), and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained (page 35, noise removal algorithms, real data to be use).

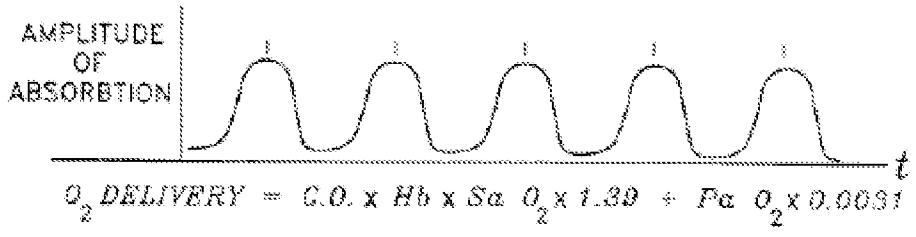


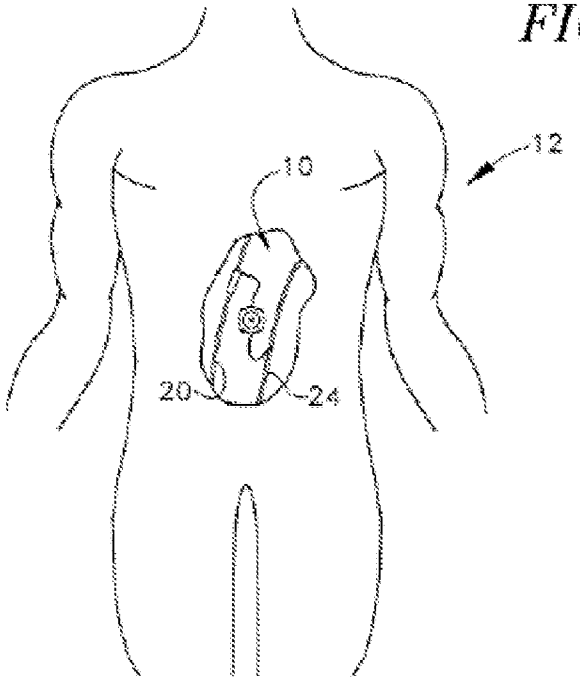
FIG. 13b

Regarding claim 58, Joseph Jeffrey further describes a calibration module (fig. 13a, unit 400) configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point (page 28, 31, 34, 35, 36 weekly calibration if needed using blood for glucose information, claim 24), wherein the reference data point and the sensor data point are obtained at substantially corresponding times (fig. 13d, 13b), and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained (page 35, noise removal algorithms, real data to be use).

Regarding claim 59, Joseph Jeffrey further describes a conversion function module configured to create a conversion function based at least in part on at least one sensor data point (page 35, multispectral correlation), wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold (page 35, noise removal algorithms, real data to be use), and wherein the conversion function is configured to convert the sensor data point into a calibrated data point (page 35, noise removal algorithms, real data to be use).

Regarding claim 60, Joseph Jeffrey further describes a sensor data transformation module (page 35, multispectral correlation) configured to convert at least one sensor data point into a calibrated data point (page 35, noise removal algorithms, real data to be use), wherein the rate of change of the data stream at the time at which the sensor data point is obtained is below a threshold (page 35, noise removal algorithms, real data to be use).

FIG. 1



Regarding claim 61, Joseph Jeffrey further describes a calibration module configured to form a calibration set based at least in part on at least one matched data pair (page 25, to calculate pulse wave velocity from sensor pair, page 35, multispectral correlation), the matched data pair comprising a reference data point and a sensor data point (page 35, noise removal algorithms, real data to be use), wherein the reference data point and the sensor data point are obtained at substantially corresponding times (fig. 13b, 13d); and a calibration evaluation module configured to evaluate the matched pair (page 25, to calculate pulse wave velocity from sensor pair, page 35, multispectral correlation), wherein the calibration evaluation module is configured to prevent the matched data pair from influencing the calibration set if the rate of change of the data stream at the time the sensor data point is

obtained is above a threshold (page 35, noise removal algorithms, real data to be use).

Regarding claim 62, Joseph Jeffrey further describes a clinical module (fig. 1, unit 10) configured to compare a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable (page 35, noise removal algorithms, real data to be use),

wherein the second reference data point is obtained prior to obtaining the first reference data point, and wherein the first reference data point is determined to be clinically acceptable if the difference between the first reference data point and the second reference data point is below a threshold (page 35, noise removal algorithms, real data to be use).

Regarding claim 63, Joseph Jeffrey further describes a clinical module (fig. 1, unit 10)configured to compare a first sensor data point to a second sensor data point to determine whether the first sensor data point is clinically acceptable (page 35, noise removal algorithms, real data to be use), wherein the second sensor data point is obtained prior to obtaining the first sensor data point (fig. 13b, 13d, signal are sequential in time to compare for noise), and

wherein the first sensor data point is determined to be clinically acceptable if the difference between the first sensor data point and the second sensor data point is below a threshold (page 35, noise removal algorithms, real data to be use).

Regarding claim 64, Joseph Jeffrey further describes a stability module configured to determine whether the sensor data is stable (page 35, noise

removal algorithms, digital bandpass), wherein the sensor data is determined to be stable if the rate of change of the data stream is below a threshold at the time the sensor data is obtained (page 35, noise removal algorithms, real data to be use).

Regarding claim 65, Joseph Jeffrey further describes the analyte comprises glucose (page 35), wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 35), and wherein the threshold is set at a predetermined level (page 35).

Regarding claim 69, Joseph Jeffrey further describes a user interface (fig. 18A, 18b), wherein the user interface is configured to request additional reference data when the rate of change of the data stream is below a predetermined threshold (page 35, noise removal algorithms, real data to be use) .

Regarding claim 73, Joseph Jeffrey further describes a user interface (fig. 18A, 18b) configured to display (page 24) continuous glucose sensor data (fig. 13b, 13d) and single point glucose monitor data (fig. 18A, unit 420, 13b, 13d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

a. Claims 66, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joseph Jeffrey (WO 97/01986, January 23, 1997) in view of B. Aussedat (A user-friendly method for calibrating a subcutaneous glucose sensor-based hypoglycaemic alarm, *Biosensors* & *Bioelectronics* Vol. *12. No.* I I, pp. 1061-1071, 1997, 1997 Elsevier Science Limited).

Regarding claim 66, Joseph Jeffrey further describes the analyte comprises glucose (page 35), wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 10, 35),
Joseph Jeffrey does not describe the threshold is 0.25 mg/dL/min, B. Aussedat describes threshold can be calculate from any giving value (fig. 1) according to how one define the boundary and needs (fig. 1).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Joseph Jeffrey and B. Aussedat to have the threshold is 0.25 mg/dL/min in order to be more flexible according to one needs and the matter of design choice (In re Ieshin,125 USPQ 416).

Regarding claim 67, Joseph Jeffrey further describes wherein the analyte comprises glucose (page 10, 35), wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 10, 35),

Joseph Jeffrey does not describe the threshold is 0.5 mg/dL/min, B. Aussedat describes threshold can be calculate from any giving value (fig. 1) according to how one define the boundary and needs (fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Joseph Jeffrey and B. Aussedat to have the threshold is 0.5 mg/dL/min in order to be more flexible according to one needs and the matter of design choice (In re Ieshin,125 USPQ 416).

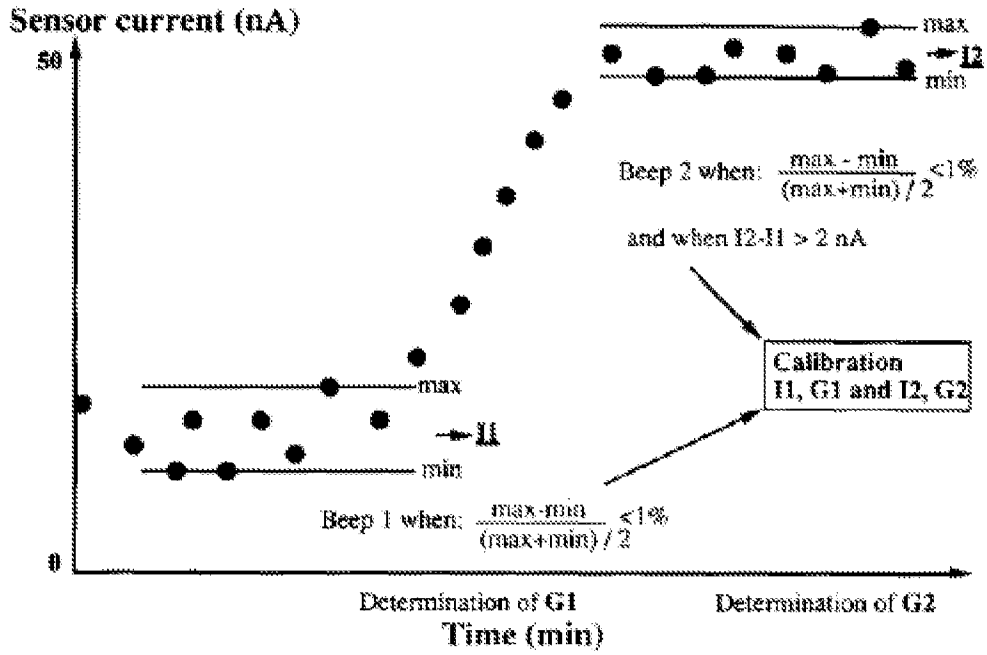


Fig. 1. Principle of the plateaus recognition performed by the ECU.

Regarding claim 68, Joseph Jeffrey further describes wherein the analyte comprises glucose (page 10, 35), wherein the data stream comprises measurements indicative of in vivo glucose concentration (page 10, 35),

Joseph Jeffrey does not describe the threshold is greater than 0.5 mg/dL/min, B. Aussedat describes threshold can be calculate from any giving value (fig. 1) according to how one define the boundary and needs (fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Joseph Jeffrey and B. Aussedat to have the threshold is greater than 0.5 mg/dL/min in order to be more flexible according to one needs and the matter of design choice (In re Ieshin,125 USPQ 416).

35 U.S.C. 103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. 103 (in light of KSR v. Teleflex, See MPEP 706.02(j)), the examiner should set forth in the Office action:

1. the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
2. the difference or differences in the claim over the applied reference(s),
3. the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
4. an explanation >as to< why >the claimed invention would have been obvious to< one of ordinary skill in the art at the time the invention was made.

Joseph Jeffrey and B. Aussedat are analogous art because they are from the same field of endeavor, glucose monitor device. (MPEP 706.02(j))

Contact information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S. Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on 571-272-2312. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Tung S. Lau/
Primary Examiner, Art Unit 2863
April 8, 2009